510(k) Summary: *syngo*.MR Oncology

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA
Registration Number	2240869
Manufacturer	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany
Registration Number	8010024
Contact Person	Ms. Nadia Sookdeo Technical Specialist Regulatory Affairs/Clinical Affairs Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA Phone: (610) 448-4918 Fax: (610) 448-1787 Email: nadia.sookdeo@siemens.com
Device Name	*syngo*.MR Oncology
Classification Name:	Picture Archiving and Communications System (PACS)
Classification Panel:	Radiology
Regulation number:	21 CFR § 892.2050
Device Class:	II
Product Code:	LLZ, LNH

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use:
syngo.MR Oncology is a *syngo*.via-based image viewing, processing and reading software. This software allows for oncological MR image evaluation in a structured way. It is a reading application primarily for convenient reading of MR scans of single or multiple body regions up to the entire body which have been acquired for clinical purposes such as oncological screening, staging and grading. The reading application does not block the display of data from other modalities that *syngo*.via supports.

syngo.MR Oncology is designed to support the oncological workflow including interpretation and evaluation of examinations, and follow-up documentation of findings.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo*.MR Oncology is a tool to support the standard practices and visual comparisons.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Device Description
In addition to the reading and reporting functions/tools that are available in the predicate *syngo*.via basic software configuration, Siemens Healthcare intends to offer MR specific workflow configurations that are adapted for MR Oncology (*syngo*.MR Oncology).

syngo.MR Oncology is a *syngo*-based image viewing, processing and reading software. This software allows for oncological MR image evaluation in a structured way. It is a reading application supporting convenient reading of MR scans of single or multiple body regions, up to the entire body which have been acquired for clinical purposes such as oncological screening, diagnosis and staging.

The medical device software *syngo*.MR Oncology consists of the following two applications: *syngo*.MR Onco Workflows and the *syngo*.MR 3D Lesion Segmentation Tool.

The *syngo*.MR Onco Workflow application consists of the following tools: MR Onco Multi-Region, MR Onco Liver, MR Onco Brain, MR Onco TimCT and an Onco report.

The *syngo*.MR 3D Lesion Segmentation Tool also known as MR Segmentation tool, is a tool using the Random walker algorithm (default algorithm) or the Level Set algorithm. 3D Lesion Segmentation provides convenient volumetric evaluation of lesions and/or other structure of interest as well as a particularly useful tool for oncology applications (for example volumetric evaluation of tumors, lymph nodes and metastases), and non-oncology lesions or other structures of interest with sufficient contrast to surrounding tissue.

General Safety and Effectiveness Concerns:
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practice and standards.

Substantial Equivalence

The *syngo*.MR Oncology is substantially equivalent to the following devices:

Predicate Software Name	510(K) Clearance Number	510(k) Clearance Date
Software *syngo* MR B17	K082427	November 7, 2008
Software *syngo.x* (*syngo*.via)	K092519	August 27, 2009
Software *syngo* PET&CT Oncology	K093621	February 23, 2010
Syngo Dosimetrist Workspace v2.7	K101119	June 6, 2010

In summary, modifications made to the predicate device software do not affect the intended use of the device nor alter its fundamental scientific technology. Siemens believes that the subject software (*syngo*.MR Oncology) is substantially equivalent to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Nadia Sookdeo
Technical Specialist
Regulatory & Clinical Affairs
Siemens Medical Solutions USA, Inc.
Customer Solutions Group
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

JAN - 6 2012

Re: K111861
Trade/Device Name: *syngo.* MR Oncology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 7, 2011
Received: December 8, 2011

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K111861

Indications for Use Statement

510(k) Number (if known): K111861

Device Name: *syngo* MR Oncology

Indications for Use:

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syngo.MR Oncology provides analytical tools to help the user assess and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations.

syngo.MR Oncology is designed to support the oncological workflow including interpretation and evaluation of examinations, and follow-up documentation of findings.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo*.MR Oncology is a tool to support the standard practices and visual comparisons.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111861/S1

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